Section 3, Remarks:

REMARKS

Reconsideration of the Final Restriction Requirement and the Final Rejections are respectfully requested in view of the amendments to the claims presented herewith, and the following remarks.

I. The Restriction Requirement of Claim 5 is Unfounded and Should be Withdrawn.

A. The Restriction Requirement is Based on Speculation, Not Science.

The Restriction Requirement, on page 4 of the Detailed Action, makes a scientifically unsupported statement as the basis of restricting claim 5 as between benzoic acid and boric acid anti-microbial agents. The Office Action asserts, emphasis added:

> "The claimed product ***can be employed*** in a materially different process, such as ***insertion of the cotton roll impregnated with*** the antimicrobial agent, ***benzoic acid, directly into a wound as a plug to promote antimicrobial action and healing***."

Contrary to that statement, Dr. Richard M Stillman, MD, FACS, Chief of Staff, Medical Director, Wound Healing Center, Department of Surgery, Northwest Medical Center, in a WebMD article entitled Wound Care, http://www.emedicine.com/med/topic2754.htm, last updated June 8, 2006, states, in Section 6 (of 11), Treatment, emphasis supplied::

> "Wound infection requires surgical debridement and appropriate systemic antibiotic therapy. ***Topical antiseptics are usually avoided because they interfere with wound healing because of cytotoxicity to healing cells.***

Thus, the medical field knows that topical antiseptics such as benzoic acid can interfere with wound healing, not promote it.

He also instructs, in that same section, emphasis supplied:

> **Remove foreign bodies**
> Be attentive to the possibility of foreign bodies, which may prevent healing of traumatic wounds, including road debris and retained ***fragments of dressing materials*** or suture material.

Therefore stuffing a wound with a cotton roll, which is the same material as a dressing bandage, is the opposite of what should be done to promote wound healing. In essence the medical field says to close wounds, not force them open.

Dr/ Stillman warns, in that same section:

> **Provide a moist (not wet) wound bed**

Therefore, one would not insert a fluid-loaded cotton roll that expresses fluid into the wound, thus wetting it.

Dr. Stillman, MD, FACS, is a member of the following medical societies: American College of Angiology, American College of Surgeons, American Medical Association, Association for Academic Surgery, Florida Medical Association, and Society of University Surgeons

Further, mouthwashes, such as benzoic acid containing mouthwashes, are well known to cause perioral contact dermatitis. See, for example, Contact Dermatitis, by Mark A Crowe, MD, Assistant Clinical Instructor, Dept.of Medicine, Div. of Dermatology, Univ. of Washington School of Medicine, a WebMD article at http://www.emedicine.com/ped/topic2569.htm ,Last Updated: March 10, 2006, wherein it is stated, in section 3 (of 11), emphasis supplied:

> ***Many substances can produce an allergic contact dermatitis***. The patient's age and the location and appearance of the dermatitis frequently lead the history in a particular direction. For example, ***if the dermatitis is perioral***, the history might include exposure to pacifiers, bubble gum, musical instruments played with a mouthpiece, toothpaste, ***mouthwashes***, lip licking habits, hobbies with mouthpieces (eg, snorkeling, diving), lipstick, lip balms, products applied to treat the symptoms, sucking limes and lying in the sun, and eating foods such as mangos (specifically exposure to the skin rind of the mango).

The sum of these citations show that the claimed delivery system could not be used in the allegedly materially different process, namely "***insertion of the cotton roll impregnated with*** the antimicrobial agent, ***benzoic acid, directly into a wound as a plug to promote antimicrobial action and healing***" as there is no credible scientific basis for that statement. The statement was speculation and as such cannot support a restriction requirement that serves no purpose in advancing the prosecution. Failing support, the Restriction Requirement must be withdrawn.

B.The Restriction is Based on a Mis-Characterization of the Invention.

The Restriction Requirement is based on the PTO view that the invention is a chemical case directed to a new composition of matter. That is, the Restriction is based on looking at an active component of the treatment anti-microbial and dividing the case along chemical compound lines. Thus, the Restriction states, page 4 of the Detailed Action:

> "It is again stated on the record that intended uses or intended function ***of a composition*** do not impart patentable distinction ***unless*** they structurally or materially alter the physical nature ***of the composition***."

But the invention is directed to a novel delivery system, a platform for targeted

delivery, over extended treatment periods (unlike the present art of use of mouthwoash), of topical, oral antimicrobial compositions, applied in a specific location in the body to provide slow release of the composition to specific soft tissues to treat a specific disease condition for people in need of treatment, and the cotton roll, by its size and treatment positioning, serves to open the sulcus groove for access of the antimicrobial to effect treatment. .

It is inappropriate for the PTO to mischaracterize the invention so it can then ignore the claim language describing the targeted delivery system. Nor is it appropriate for the Office to say that the language it mischaracterizes merely sets forth an intended use or function, which it can now conveniently ignore.

A proper restriction might be between different modalities of delivery, not between one or the other ingredient of a variety of compositions that are delivered by the claimed delivery system. Sincer there is but one modality claimed, no restriction is needed or appropriate.

Delivery systems are cognizable as patentable inventions. Thus, a hypodermic is a delivery system, and an epidermal patch is another. A pill is another and a pressurized transdermal fluid injection gun is another. Microcapsules of medicines in which the capsule wall contains iron particles so that injected microcapsules can be concentrated by an externally applied magnetic field at a particular location in the body is still another. X-ray is another.

But all of these have a medical treatment context that is not ignored in their consideration. So here, the specific limitations relating to the targeted delivery of what, where in the body and for how long to treat what condition, is not a mere intended use, but is the context that brings life and meaning to the claim and must be given weight, ***Pitney Bowes, Inc. v. Hewlett-Packard, Co.*, 182 F. 3rd 1298 (Fed. Cir. 1999).**

Therefore, restriction along the line of one component of one of many antimicrobial solutions that may be target-delivered by the claimed delivery platform to the specific tissue for the extended treatment period in the specific location in the body for treatment of a specific condition completely ignores the delivery aspect of the invention. The Restriction Requirement, properly and repeatedly traversed, should be reconsidered and withdrawn.

II. Citation of 37 C F R §1.3.

A brief comment in response to the citation of 37 CFR §1.3. Applicant is puzzled by the inappropriateness of that citation, particularly in view of Examiner Low's (we believe it

was him, although there is reference to an "Examiner Woodward" in the Interview Summary; Applicant understood there were only 2 examiners present: Low and Royds; clarification is requested) telling Applicant and Dr. Novotny to "shut up" in the interview. If an Examiner Woodward was also present, then it might have been him. It was not Examiner Royds.

Since there is an evident lack of respect for the invention on the part of the Examiners assigned to the case, it is respectfully suggested that the case be reassigned.

III. Claims in the Case:

Claims 1 – 15 remain in the case, with claim 5 provisionally withdrawn pending resolution of the Restriction Requirement issue, see above.

The method of treatment claims 16 – 20 have been canceled in favor of prosecution in a co-pending Divisional case.

IV. Additional Claim Amendments are Supported; Entry for Appeal is Requested.

Claims 1, 2, 5, 10, 11, 12 and 13 have been amended to more clearly point out and distinguish the delivery system of the invention over the references to individual chemical compounds and compositions. Entry and allowance is respectfully requested as the amendments are fully supported in the Specification, Claims and Drawings as originally filed and the amendments are not directed to a different invention.

In any event, entry of the amendments to put the case in better condition for appeal is requested.

Main claims 1 and 10 have been carefully amended in response to the Office Action treatment of the claim limitations as mere statements of intended use. As amended, the claims point out that the delivery system is targeted to the specific application of treatment of specified oral conditions/diseases of bad breath and gingivitis, both resulting from microbial proliferation on the soft tissue and in the gingival sulcus. The delivery system is specified as a manual, single dosage-unit, sterile cotton roll of defined configuration for insertion and comfortable retention in a buccal vestibule of a person having the adverse condition and in need of treatment. The cotton roll is constructed to retain its integrity during use and to resist the action of the buccinator muscle that massages the roll to express the medication composition. The roll is specifically configured for the special location and massaging action of the buccinator muscle, and thereby cooperates with the body. The configuration permits a slow, long term substantially continuous release of the medication into contact with the

affected tissues to effect the treatment without interfering with or restricting ordinary life activities.

The language of the claim amendments is supported in the Specification and drawings as a whole, Specific terms are supported, inter alia, in the Specification text as follows:

- Manual: page 5, line 16; fingers, pg 2, line 26;
- Single-use and dosage units: page 2, l 25; p 6, l 7 and 33; p 6, 20, 26; p 13, l 3;
- Adverse conditions: p 6, l 25-26;
- Bad breath and gingivitis: p2, l 34 through p 3, l 1;
- Periodontal, periodontal disease, periodontal conditions: p 1, l 14 and 19; p 2, l 34; Original claim 1;
- Platform for delivery: p 2, l 33-34;
- Sterile: p 10, l6;
- Inserted (insertable): p2, l 25;
- Buccal vestibule: p 3, l 29;
- Sulcus, sulcus groove: p2, l 5 – 6 and l 27;
- Buccinator massaging the roll opens the sulcus groove for delivery of medication thereinto: p3, l 26 – 32; p 5, l 25 – 30; p 8, l27 through page 9, l 1;
- Targeted and targeted location: p 2, l 15; p 3, l 1;
- Roll functions as a source for the medicinal fluid: p2, l 23–30; p 12, l 12 – 18;
- Retain integrity: p 8, l 9 – 10;
- Extended treatment period: p 2, l 23; p 3, l 2;
- Treatment for an hour: p5, l 28;
- Targeted, concentrated application directly at point of need: p 8, l30 – 32; p12, l 8;
- Releasably absorbed in the cotton roll: p 8, l 6; p 11, l 12;
- Patient can carry on normal daily activities, including speaking: p 2, l 30; p 3, l 10 – 14; p 12, l 12;
- Shirt-pocket sized pouches with tear off strip: p 6, l 31 – 33.

Accordingly, no new matter has been added, and these amendments clarify inventive features of the claimed delivery system platform and portable consumer package for any-time use availability of the treatment medication for targeted application by the patient in need of

treatment.

Further, the amendments do not define a different invention. ***In re Wright***, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir.1989). As stated in ***In re Smith***, 481 F.2d 910, 914, 178 USPQ 620, 624 (CCPA 1973), and ***In re Ruschig***, 54 CCPA [1551] at 1559, 379 F.2d [990] at 996, 154 USPQ [118] at 123, "the claimed subject matter need not be described in ***haec verba*** in the specification in order for that specification to satisfy the description requirement." As amended, the instant claims describe the invention consistent with the essence of the original disclosure. There is clear compliance with the description requirement.

V. Response to the New 103 Rejection of Claims Over a Combination of 6 References.

The application clearly points out that the problem with commercially available fluid mouthwash compositions is that merely swishing them around in the mouth is essentially cosmetic, and has little therapeutic benefit. In contrast, the invention provides a delivery system that solves that problem with improved results of effectiveness at lower dosage (See Specification at pages 3, 12 and 13), and none of the cited references taken alone or together teach or suggest the inventive solution, regardless of the unsupported speculation of the Examiner as to what those skilled in the art could do.

In addition, the inventive targeted delivery system permits the user to move around, drive around, and talk. Essentially, using the inventive targeted delivery system, the user can carry on normal daily activities while being treated. In contrast, using the prior art mouthwash, the user must hang around one's sink, resist the "burn" as long as he/she can stand it, then spit it out. The prior art treatment period is 30 seconds or less. With the inventive delivery system, the treatment period can be 5 minutes to an hour or more, as needed or desired.

The 6-reference rejection is exemplary of a "bag-of-parts" approach to Office Action §103 rejections. Such rejections take the position that if one element of a combination is found, then not only are all other components obvious, but all the relationships between the parts are obvious, all the functions of the parts are obvious, all the motivations for selecting only those selected parts out of diverse references are obvious, and the unique way in which they are to be assembled to arrive at the claimed combination is obvious.

The bag of parts approach is not the law.

The fundamental principle, as articulated by the Court of Appeals for the Federal

Circuit in **In re Gordon,** 221 USPQ 1125 (Fed. Cir. 1984), is that the prior art must suggest the combination of references. In **Gordon,** the Court rejected the idea that the prior art devices could be modified to produce the claimed device as a proper basis for an obviousness rejection, holding the combination is not proper unless the prior art suggests the desirability of such a modification. In **SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.,** 8 USPQ2d 1468 (Fed. Cir. 1988), the Court held that to pick and chose elements from references to recreate the invention is not proper. And in **Northern Telecom, Inc. v. Datapoint Corp.,** 15 USPQ2d 1531 (Fed. Cir. 1990), **cert. denied,** 498 U.S. 920 (1990), the Court held that "[i]t is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor." (Emphasis added).

These governing principles were applied by the Court in holding in error the obviousness rejections in **In re Bond,** 15 USPQ2d 1566 (Fed. Cir. 1990) and **In re Mills,** 16 USPQ2d 1430 (Fed. Cir. 1990). **In re Mills** specifically held that although the prior art device could be modified to run the way the applicant's device was claimed to run, "there must be a suggestion or motivation ***in the reference*** to do so." 16 USPQ2d 1430. Since there was none, the rejection was in error and was reversed. More recently, in **Sensonics, Inc. v. Aerosonic Corp.,** 38 USPQ2d 1551 (Fed. Cir. 1996), the Court reiterated this principle, holding there was no teaching or suggestion in the prior art that would have led a person skilled in the art to select the specific mechanical and electrical structures and concepts and combine them in the manner of the invention of that case.

As a further principle, both the Courts and the Board of Appeal have long held that the suggestion for the combination in the references cannot come from the Applicant's Specification, see, for example, **Ex parte Brack,** 134 USPQ 445 (POBA 1961). The reason is simple: Applicant's Specification is not prior art. **Applicant's specification cannot be used as a parts-list to search for disparate parts in the art, and then used as a blueprint to assemble the selected parts.** ***The sources for the motive to select the parts and to reassemble them to obtain the desired result must come from the references.***

The above principles were not followed in this Office Action. There is no teaching in any of the references pointing to the other. The only reason for combining them comes from Applicant's own specification. That is improper. The result is that the rejection is unsound and should be withdrawn.

Masci is directed to controlling bacteria by use of a known decamethylene 1, 10-bis-t-aminoquinaldinium salt (DMAA). Masci discovered that by adding a cetyl pyridinum salt, he could reduce the DMAA concentration to provide a desired level of antimicrobial activity in compositions containing these salts (Col 1, lines 10 -- 60). Thus, Masci is directed to a chemical formulation. Only incidentally in Column 8 does Masci mention that in a dry powder it can be "incorporated in or applied to articles, such as dental aids and the like including cotton rolls, pledgets, sponges, cones and points or similar articles composed of cellulose or other materials." That is an invitation to experiment, not a teaching of the use of cotton rolls as a delivery platform for treatment of bad breath and gingivitis to use an anti-microbial composition in fluid form placed in a specific oral location (a buccal vestibule) in a treatment amount designed for treatment of those specified conditions over an extended period with better results than conventional oral mouthwash.

Thus, this Office Action substitutes Masci in place of Kazdan as the primary reference. Kazdan used a dry powder composition with pumice and sugar as a tooth cleaner. Now we have a different dry composition in Masci, but for no specified use. Dry compositions are not claimed.

The 5 secondary references of **Weisel, Vermeer, Julius, Speaker and Copelan** have all been previously discussed in Applicant's responses dated June 5, 2006, March 28, 2006, and February 16, 2006. Those comments are incorporated by reference here to not burden the record.

Weisel is directed to white strips. No teaching of buccal vestibular use, shape, functionality. This is a tooth care reference. What it teaches in combination with Masci is that the Masci DMAA + cetyl pyridinum salt might be put on Weisel's strips (but for a different, unknown purpose); OR that the Weisel's whitner could be put on Masci's rolls, pledgets, sponges, cones and points to be used in some unknown manner. Neither is the claimed invention. And Masci does not teach his composition will whiten teeth, or how Weisel's composition on Masci's rolls could be used to whiten teeth. Weisel does not cure the defects in Masci.

Indeed, the quoted reference to Weisel on page 9 of the Office Action supports a holding of patentability. As the PTO notes, Weisel teaches moutwashes are easily washe from the site of infection by salivation and routine mastication. Thus, Weisel would teach one of ordinary skill in the art to not use the cotton roll of Masci with his composition com-

bination DMAA+ CPS wither dry or in fluid form as it would be washed away. But Applicant specifically teaches that the cotton roll, saturated as it is with the fluid composition, acts as a reservoir that continuously bathes, throughout an extended treatment period, the affected soft and sulcus tissue precisely where the diseased tissue is. The reservoir is placed next to the tissue in need of treatment. Thus, Applicant has gone in a direction that Weisel, and the PTO says, do not go. That is strong evidence of patentability.

Vermeer is directed to an alkyl aldonamide compound-containing composition for mouthwash and dentifrice. Vermeer does not cure the defects of Masci. Note it distinguishes between dentifrices and mouthwashes, see columns 1 – 3. Nowhere does it suggest the combination with Masci's DMAA + CPS composition. At best, with hindsight, Vermeer might suggest using the Masci compounds in mouthwash and dentifrice. but even if it did, Applicant's invention is not directed to either. Again, the Office fails to address the delivery platform nature of the inventive combination.

Julius shows a dental sponge. What is the combination with Masci? Masci suggests use of his compounds in a sponge, and Julius tells us how to use a sponge in dental surgery? But that is not the invention.

Speaker is directed to a delivery system for topical applications comprising, not a cotton roll, but a highly viscous carrier containing dissolved or dispersed topically-active agents that are microencapsulated for sustained release. He mentions in passing **"very elaborate and somewhat uncomfortable methods of treatment"** of gingivitis, namely "**implanting in the periodontal sulcus one or more coils of an antibiotic-impregnated cotton or nylon braided cord**". Clearly a roll is not a cord, and the claimed rolls are not "coils of braided cord". More importantly, the inventive rolls are inserted in the buccal vestibules, not IMPLANTED surgically in the periodontal sulcus. It should be noted that the treatment referred-to is a surgical procedure directed to periodontitis, not gingivitis. The reference to "periodontal sulcus" indicates a pathologic condition, a 3 – 5 mm deep detachment of the tissue from the teeth and jawbone accompanied by bone loss, and not something effectively treated by mouthwash.

Copelan is directed to what appears to be a floss holder or a tongue brush, or both. Again this reference is directed to teeth, not the application-specific delivery platform combination claimed. Clearly Copelan is not resealable, and not shirt-pocket sized. Its relevance is not clear.

The rejection repeatedly refers to one teaching or another, always of course one that is missing from the references, as being "prima facie obvious to one skilled in the art"; see page 8, for example, and again refers to "use of the active composition in contact with the teeth", citing Weisel as support for the conclusion. The relevance is not understood

The rejection on pages 9 and 10 proposed to throw out Masci's composition in favour of Weisel's mention of benzoic acid. This is a transparent, improper use of Applicant's specification to pick benzoic acid out of Weisel, ignore the teaching of Weisel to whiten teeth, ignore the DMAA+CPS combination in Masci, somehow ignore Weisel's teeth, and focus on rolls in Col 8 of Masci, all for a purpose and delivery mode and location not taught by either.

That is exemplary of the problem with the Office Action in a nutshell: The mis-use of Applicant's Specification as a parts list to pick those isolated parts from the references and then use Applicant's specification as a blue print to reassemble them for a purpose not shown or suggested in the references in a manner not shown or suggested in the references, with the unexpected results not shown or suggested in the references..

In connection with the package assembly combination claims 10 – 15, the Office action states on page 13, emphasis supplied:

> "Applicant is reminded that the type of packaging in which the **composition** is retained fail to impart any physical, material or structural properties to the **composition** that are not found in the prior art of Masci et al, and therefore, do not constitute a patentable distinction over the art."

OK, lets see what that means. We, the PTO, can ignore all the physical structure (packaging form, structural elements, the number of rolls having the fluid medication in then, size, etc) recited in those claims because we choose to ignore the delivery system platform nature of the claims and decide to consider this as only a chemical compound case (note the repeated reference to "composition" in that quote), therefore the physical structure we have decided to ignore, has no patentable significance. Applicant requests the Office provide legal basis for that approach to examining the case. That statement in the Office Action is merely a way to rely on phantom prior art, which is improper, as pointed out by Applicant in one or more prior responses.

In addition, the rejection repeatedly improperly uses improved results as a basis for providing the "motivation" to combine references that is required by law. But the law states that the motivation must come from the references, not out of mid air or the desire for better

results. That is no different from the prior Office Action asserting that the combination ***flows*** logically from the desire to enhance one feature or another. The mere fact that something existed in the prior art, assuming arguendo that it did, does not provide motivation. **That is, existence of a part is not motivation for a combination. Nor is the Applicant's showing of improved and unexpected results (see Specification, and particularly pages 3, 12 and 13, discussing actual results) the proper basis for finding motivation to combine the references. The Office is respectfully requested to cite a CAFC case that says it is a proper basis (not *ex cathedra* MPEP language, or the Examiner's "deeming" something obvious).**

The Office Action makes repeated reference to a use or combination of teachings of references as "would have been *prima facie* obvious to one of ordinary skill in the art because the skilled artisan would have been motivated" to do something not taught in the references: e.g., to facilitate distribution of cotton rolls; to preserve sterility; to retain efficacy; to enhance absorbency; to enhance the amount of active antiseptic composition entrained in the cotton roll; to sustain localized topical delivery; to eliminate any lint left behind; and because there would have been a reasonable expectation of success.

The problem with that approach is that it does not satisfy the requirements of a *prima facie* case. That is, for the Office to make a *prima facie* case, it must rest on proven facts, not opinion or conjecture of the Examiner. Mere unsupported assertion arising out of the properties of a compound *per se* do not support obviousness of a combination rejection, much less rebut unexpected results. It is procedurally impossible for an Applicant to rebut a non-properly proven *prima facie* case where there is no evidence.

Rather, what the PTO is doing here is to look at Applicant's specification, note all the advantages and unexpected results Applicant shows arise from the inventive combination and method, then allege that one skilled in the art (or the new standard person "the skilled artisan"; is the standard ordinary skill or skilled artisan?) would have a reasonable expectation of success precisely because Applicant was the first to teach that.

The alleged "*prima facie*" cases are flawed, have not been proved, and the PTO has not rebutted Applicant's evidence of actual use and improved, unexpected results in the Specification. The Office can no more "deem" its burden of proof *prima facie* met than it can deem the invention obvious. The Board of Patent Appeals and Interferences does not

condone that approach, stating in ***Ex parte Stern*, 13 USPQ 2d 1379 at 1381:**

> "The examiner should be aware that " deeming" **does not discharge him from the burden of providing the requisite factual basis and establishing the requisite motivation to support a conclusion of obviousness.** [Citing cases] The examiner's reference to unidentified phantom prior art techniques falls far short of the mark. [Citing cases] **Accordingly, the examiner's rejection** of the appealed claims under 35 USC 103 as unpatentable over any of the primary references, considered singly, **is reversed."**

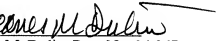
CONCLUSION

It is Applicant's position that the case is now in complete condition for allowance as the rejections are unsound or have been rendered moot. Favorable action of allowance is respectfully requested.

In addition, in the event that there remain any open issues, the Examiner is requested to expedite the prosecution of this case by calling undersigned counsel for Applicant.

Respectfully submitted,
Jacques M. Dulin

Date: September 18, 2006

by: 
Jacques M. Dulin, Reg. No. 24,067
Attorney for Applicants

Jacques M. Dulin, Esq.
Innovation Law Group, Ltd.
237 North Sequim Avenue
Sequim, WA 98382-3456

e-mail: Dulin@InnovationLaw.com

Phone #: 360/ 681-7305
Fax #: 360/ 681-7315

End of Section 3, Remarks

End of Response to Office Action